REMARKS

Claim 1 has been amended. Support for the amendments can be found throughout the application as filed. Claims 25-28 have been cancelled without prejudice or disclaimer. Now pending in the application are claims 1-7, 9-18, 20-24, 29-31, 33-35, 37, 39-41 and 44-49. No new matter has been added. Applicants submit that the amendments presented herein may properly be entered pursuant to 37 CFR 1.116, as they cancel certain claims and reduce issues for appeal or put the claims in better condition for allowance. Entry and consideration of the amendments and arguments presented herein is therefore requested.

The amendments to and cancellations of certain claims are being made for the purpose of expediting prosecution and are made without prejudice or waiver. Applicants reserve the right to present the original or previously-pending claims in this or a continuing application.

Applicants note with appreciation that the previous rejection of claims under 35 U.S.C. § 102(b) as anticipated by Zhao *et al.* (J. Med Chem. 2000), has been withdrawn.

Rejections under 35 USC §112, first paragraph

Claims 30, 31, 33-35, 37 and 39-41 have been rejected under 35 U.S.C. §112, first paragraph. In the Examiner's view (as stated in the Office Action dated March 3, 2004), "the specification . . . does not reasonably provide enablement for all neurodegenerative diseases, psychiatric dysfunctions, dopamine dysfunctions, [and] cocaine abuse." The Examiner has further stated that

> there is no teaching either in the specification or prior art that serotonin uptake and/or dopamine uptake inhibitors are either well known to have therapeutic utility in treating every known neurodegenerative disease, psychiatric disease, dopamine dysfunction, and cocaine abuse or have been shown to be efficacious in known animal models of every known neurodegenerative disease, psychiatric disease, dopamine dysfunction and cocaine abuse.

Office Action at page 2.

Applicants respectfully disagree.

One of ordinary skill in the art can readily determine which conditions can be treated according to the methods of the invention. For example, as the Examiner has correctly acknowledged, the compounds of the invention bind to monoamine transporters such as the dopamine transporter (DAT) and/or serotonin transporter (SERT), and one of ordinary skill in the art would know that conditions related to the DAT and/or SERT (including, e.g., dopamine dysfunctions) can be treated according to the present methods.

In addition, Applicants point out that the specification need not teach that serotonin and/or dopamine reuptake inhibitors are effective for the treatment of "every known neurodegenerative disease, psychiatric disease, dopamine dysfunctions, cocaine abuse and clinical dysfunctions," as the Examiner has stated. Applicants contend that what is required is that the scope of enablement be commensurate with the scope of the claims (se, e.g., MPEP 2164.05). This Applicants have done.

Moreover, as discussed in Applicants' previous submission, not all of the rejected claims recite the language to which the Examiner has objected. The Examiner does not appear to have addressed these claims in the present Office Action.

For example, claim 39 (and claim 40 which depends therefrom) is directed to a method of treating *dopamine related* dysfunction. As previously pointed out, the present compounds are inhibitors of the dopamine transporter and/or serotonin transporter, and Applicants respectfully contend that the method of claim 39 is amply enabled by the teachings of the present specification. The Examiner has not specifically disputed this point. If the Examiner continues to maintain this rejection, Applicants respectfully request that the Examiner point out the basis for his position that methods of treating dopamine related dysfunction would not be enabled based on the teachings of the specification.

Claim 41 is directed to a method for treating *cocaine abuse*. As described in the specification (e.g., at page 1, lines 9-25 and page 7, lines 10-13), cocaine recognition sites are localized on monoamine transporters, including the DAT, and, therefore, compounds which inhibit the DAT can be useful in the treatment of cocaine abuse. Applicants respectfully contend that the method of claim 41 is amply enabled by the teachings of the present

specification. The Examiner has not specifically disputed this point. If the Examiner continues to maintain this rejection, Applicants respectfully request that the Examiner point out the basis for his position that methods of treating cocaine abuse would not be enabled based on the teachings of the specification.

Reconsideration and withdrawal of this rejection is proper and the same is requested.

Rejections under 35 USC §112, second paragraph

Claims 25-28 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

While Applicants do not agree with the Examiner's position, these claims have been cancelled (without prejudice or waiver) solely in order to expedite prosecution of the application. This rejection is therefore moot as to these claims.

Reconsideration and withdrawal of the rejection is proper and the same is requested.

Rejections under 35 USC §102

Claims 1-29, 41, 44, and 45 have been rejected under 35 USC §102(a) as anticipated by Meltzer *et al.*, *J. Med. Chem.* 2001, 44, 2619-2635. This rejection is traversed. As previously noted, the Meltzer *et al.* paper cited by the Examiner is the work of the present inventors, published less than one year prior to the present application for patent, and accordingly cannot be cited against the present claims. Attached to this paper as Appendix A is the (unexecuted) Declaration under 37 CFR 1.132 of Peter C. Meltzer, establishing that the Meltzer *et al.* paper is not available as prior art under 35 USC § 102(a). See, e.g., *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). An executed copy of the Declaration will follow in due course.

Reconsideration and withdrawal of this rejection is proper and the same is requested.

Certain of the pending claims have been rejected under 35 U.S.C. 102(b) by Meltzer *et al.*, WO 99/02526. Applicants cannot determine which claims are rejected, as the Examiner

has merely stated that "this reference still anticipates the instant claims when R1 represents –COR3 and R2 represents –OH group in the compounds of formulae I, II and III (see pages 7-8 and claim 1 [of Meltzer WO 99/02526])." Assuming *arguendo* that the Examiner intends the rejection to apply to all pending claims, Applicants provide the following remarks.

The Meltzer WO 99/02526 reference describes tropanes and tropane analogs, but this reference does not specifically disclose the presently-claimed compounds or methods for using them. Furthermore, the broad structural formulae to which the Examiner refers cannot anticipate the more-specifically-drawn compounds (and methods of use thereof, and pharmaceutical compositions thereof) according to pending claims 1-7, 9-18, 20-24, 29-31, 33-35, 37, 39-41 and 44-45.

In order to anticipate a claim, a reference must disclose *each and every element* of the claim (see, e.g., MPEP 2131). As also provided by the MPEP in the context of anticipation of a species by a genus disclosure, "anticipation can only be found if the classes of substituents are sufficiently limited or well delineated." MPEP 2131.02 (citation omitted). Applicants respectfully contend that the present claims are not anticipated by the disclosure of the Meltzer WO 99/02526 reference. Applicants point out that the dependent claims provide additional distinction with respect to the reference disclosure.

As provided by the MPEP, an earlier genus also does not necessarily render obvious a later, more narrowly-drawn claim to species within that genus. Applicants respectfully contend that the Meltzer WO 99/02526 reference does not teach or suggest the claimed compounds (and pharmaceutical compositions and methods of use) as defined by the pending claims. Applicants point out that the dependent claims provide additional distinction with respect to the reference disclosure.

As to claims 46-49, the portions of the Meltzer WO 99/02526 reference cited by the Examiner (e.g., formulae I, II and III of Meltzer WO 99/02526) do not teach or suggest compounds having an oxo (=O) group at the 6- or 7-position of the ring system, as required by claim 46 (and claims 47-49 which depend therefrom). Thus, the Meltzer WO 99/02526 reference does not anticipate, nor render obvious, claims 46-49.

Accordingly, reconsideration and withdrawal of the rejection is appropriate and the same is requested.

Claims 1-45 have been rejected under 35 U.S.C. 102(e) as being anticipated by Meltzer (US 6,353,105; "Meltzer '105") and Meltzer (US 6,670,375; "Meltzer '375") (together the "Meltzer patents"). As with the rejection over the Meltzer WO 99/02526 reference discussed above, Applicants cannot determine which claims are rejected, as the Examiner has merely stated that "both the U.S. patents [Meltzer '105 and Meltzer '375] still anticipate the instant claims when R1 represents –COR3 and R2 represents OH group in compounds of formulae I, II and III." Assuming *arguendo* that the Examiner intends the rejection to apply to all pending claims, Applicants provide the following remarks.

The Meltzer patents describe tropanes and tropane analogs, but do not specifically disclose the specific presently-claimed compounds or methods for using them. Furthermore, the broad structural formulae to which the Examiner refers cannot anticipate the more-specifically-drawn compounds (and methods of use thereof, and pharmaceutical compositions thereof) according to pending claims 1-7, 9-18, 20-24, 29-31, 33-35, 37, 39-41 and 44-45.

In order to anticipate a claim, a reference must disclose *each and every element* of the claim (see, e.g., MPEP 2131). As also provided by the MPEP in the context of anticipation of a species by a genus disclosure, "anticipation can only be found if the classes of substituents are sufficiently limited or well delineated." MPEP 2131.02 (citation omitted). Applicants respectfully contend that the present claims are not anticipated by the disclosure of the Meltzer patents. Applicants point out that the dependent claims provide additional distinction with respect to the reference disclosure.

As provided by the MPEP, an earlier genus also does not necessarily render obvious a later, more narrowly-drawn claim to compounds within that genus. Applicants respectfully contend that the Meltzer patents do not teach or suggest the claimed compounds (and methods of use thereof) as defined by the pending claims. Applicants point out that the dependent claims provide additional distinction with respect to the reference disclosure.

As to claims 46-49, the portions of the Meltzer patents cited by the Examiner do not teach or suggest compounds having an oxo (=O) group at the 6- or 7-position of the ring system, as required by claim 46 (and claims 47-49 which depend therefrom). Thus, the Meltzer patents do not anticipate, nor render obvious, claims 46-49.

Accordingly, reconsideration and withdrawal of the rejection is appropriate and the same is requested.

Applicants further note that, because the Meltzer '105 and '375 patents were owned by the same person or subject to an obligation of assignment to the same person at the time the present invention was made, these patents therefore cannot be used in a rejection under 35 U.S.C. 103(a) because those patents would qualify as prior art, if at all, only under 35 U.S.C. 102(e)/(f)/(g). See 35 U.S.C. 103(c)(1).

Double Patenting Rejections

The Examiner has rejected claims 1-7, 9-18, 20-28, 44 and 45 under the judicially-created doctrine of obviousness-type double patenting over claims 1-11, 21, 22, 27 and 32 of the Meltzer '105 patent. The Examiner states that although the pending claims are not identical to the cited claims of the Meltzer '105 patent, "the instant claims are encompassed by broader values of variables R1 and R2 in compounds of formulae I, II and III of the cited patent, specifically when R1 represents COR3 and R2 represents OH or OR3 group." This rejection is traversed.

As the Examiner is aware, present claim 1 is directed to compounds having the structure indicated, in which the R_1 group is COR_3 and R_2 is OH or O. Applicants urge that the presently-claimed compounds represent a patentably distinct invention with respect to the claimed invention of the '105 patent, in that the invention of present claim 1 is not an obvious variation on the invention of the claims of the '105 patent. As the analysis in the context of obviousness-type double patenting is similar to obviousness rejections under 35 USC 103(a) (see, e.g., MPEP 804), Applicants refer to the discussion of non-obviousness of the claimed invention provided above, and urge that the claims are not obvious variants of the invention as claimed in the cited claims of the '105 patent. Similarly, present claim 29, directed to pharmaceutical compositions of a compound of claim 1, also is not an obvious variation on the invention of the claims of the '105 patent. An obviousness-type double patenting rejection is therefore inappropriate.

Even more, claims 2-7, 9-18, 20-24, and 44-45 further define the present invention and provide additional basis for patentable distinction over the claims of the '105 patent. For example, claims 23 and 24 are each directed to two compounds. Applicants contend that these

compounds would not have been obvious in view of the claims of the '105 patent. It is not enough for the Examiner to assert that the present claims "are encompassed by the broader values of variables R1 and R2," as stated in the Office Action; the Examiner has not provided a rationale to support the view the instant claims would have been obvious over the claims of the '105 patent. Applicants respectfully contend that the rejection cannot stand.

The Examiner has rejected claims 1-7, 9-18, 20-24, 29-31, 33-35, 37, and 39-45 under the judicially-created doctrine of obviousness-type double patenting over claims 1 and 3-22 of the Meltzer '375 patent. The Examiner states that although the pending claims are not identical to the cited claims of the Meltzer '375 patent, "the instant claims are encompassed by broader values of variables R1 and R2 in compounds of the cited patent, specifically when R1 represents COR3 and R2 represents OR3 group." This rejection is traversed.

The discussion of the non-obviousness of the claims with respect to the claims of the '105 patent is also applicable to the rejection of the present claims over the claims of the '375 patent. For at least the reasons discussed above, the present claims are not obvious in view of the claims of the '375 patent. An obviousness-type double patenting rejection is therefore inappropriate.

For at least the foregoing reasons, Applicants request reconsideration and withdrawal of the rejections.

Objection to the Claims

In the Office Action, claims 1-7, 12-17, 25-31, 33-35, 37 and 39-41 stand objected to for allegedly containing non-elected subject matter.

In response, claim 1 has been amended to remove the recitation that X can be $C=CX_1Y$. Applicants submit that the claims do not contain non-elected subject matter, and that the objection has been overcome. Reconsideration is requested.

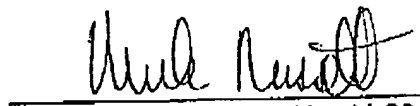
CONCLUSION

It is respectfully submitted that this application is in condition for allowance. Early and favorable action is earnestly solicited.

It is not believed that any additional fees are due, however if additional fees are due please charge our Deposit Account No. 04-1105. The undersigned requests any extensions of time necessary to avoid abandonment of this application.

If the Examiner considers that issues remain, he is invited to contact the undersigned at the telephone number below.

Respectfully submitted,



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